DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 3 2012

Re: VIIBRYD
Patent Nos. 5,532,241 and 7,834,020
Docket Nos. FDA-2011-E-0380 and
FDA-2011-E-0389

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,532,241 and 7,834,020, filed by Merck Patent GmbH, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for VIIBRYD (vilazodone hydrochloride), the human drug product claimed by the patents.

The total length of the regulatory review period for VIIBRYD (vilazodone hydrochloride) is 4,778 days. Of this time, 4,472 days occurred during the testing phase and 306 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 24, 1997.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 1997

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 22, 2010.

   FDA has verified the applicant's claim that the new drug application (NDA) for VIIBRYD (NDA 22-567) was submitted on March 22, 2010.

3. The date the application was approved: January 21, 2011.

   FDA has verified the applicant's claim that NDA 22-567 was approved on January 21, 2011.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Danielle L. Herritt
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